



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steven B. Landau
Application No.: 10/757,364 Group Art Unit: Unknown
Filed: January 13, 2004 Examiner: Unknown
Confirmation No.: Unknown
Title: METHOD OF TREATING FUNCTIONAL BOWEL DISORDERS

CERTIFICATE OF MAILING OR TRANSMISSION	
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
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Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for references AN2 and AM3 under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☒ the enclosed English language abstracts.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. 10/757,981, by Landau *et al.*, filed January 13, 2004, Docket No.: 3506.1001-002

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

[X] A copy of the above-cited application, including the current claims, is enclosed.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Remarks

References AX4 and AY4 are copies of the British priority documents for International Application No. PCT/GB2003/002974 (WO 2004/004734 A1, published on January 15, 2004, Reference AL2). Copies of priority documents for international applications filed under the Patent Cooperation Treaty are available through WIPO upon publication of the international application pursuant to Rule 17.2(c) PCT. Copies of References AX4 and AY4 were obtained in this manner.

Method of payment:

[] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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3506.1000-002APPLICATION NO.
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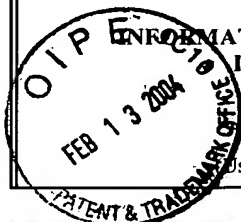
U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,695,568	09-22-1987	Ninomiya <i>et al.</i>
	AB	4,939,136	07-03-1990	Haeck <i>et al.</i>
	AC	5,225,407	07-06-1993	Oakley <i>et al.</i>
	AD	5,352,685	10-04-1994	Maruyama <i>et al.</i>
	AE	5,434,174	07-18-1995	Gidda <i>et al.</i>
	AF	5,438,068	08-01-1995	Eeckhout <i>et al.</i>
	AG	5,470,868	11-28-1995	Young
	AH	5,576,317	11-19-1996	Gonsalves
	AI	5,663,343	09-02-1997	van der Meij <i>et al.</i>
	AJ	5,945,415	08-31-1999	Kato <i>et al.</i>
	AK	5,962,494	10-05-1999	Young
	AA2	5,977,175	11-02-1999	Lin
	AB2	5,985,866	11-19-1999	Müller <i>et al.</i>
	AC2	5,990,159	11-23-1999	Meulemans <i>et al.</i>
	AD2	6,054,461	04-25-2000	Fairbanks <i>et al.</i>
	AE2	6,117,879	09-12-2000	Fairbanks <i>et al.</i>
	AF2	6,156,771	12-05-2000	Rubin <i>et al.</i>
	AG2	6,235,745 B1	05-22-2001	Megens
	AH2	6,284,770 B1	09-04-2001	Mangel <i>et al.</i>
	AI2	6,300,336 B1	09-04-2001	Eeckhout <i>et al.</i>
	AJ2	6,355,647 B1	03-12-2002	Steiner <i>et al.</i>
	AK2	6,384,042 B2	08-27-2002	Färber <i>et al.</i>
	AA3	6,429,209 B2	08-06-2002	Mangel <i>et al.</i>
	AB3	6,440,453 B1	08-27-2002	Fischer <i>et al.</i>
	AC3	6,441,038 B1	08-27-2002	Loder <i>et al.</i>
	AD3	6,458,795 B1	10-01-2002	Bergeron, Jr.

EXAMINER

DATE CONSIDERED

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EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	6,465,458 B1	10-15-2002	Wong <i>et al.</i>
	AF3	6,566,369 B2	05-06-2003	Cautreels <i>et al.</i>
	AG3	6,588,708 B1	05-06-2003	Lin
	AH3	2001/0020025 A1	09-06-2001	Megens
	AI3	2001/0044450 A1	11-22-2001	Mangel <i>et al.</i>
	AJ3	2001/0056110 A1	12-27-2001	Faerber <i>et al.</i>
	AK3	2002/0002197 A1	04-04-2002	Mueller <i>et al.</i>
	AA4	2002/0040033 A1	04-04-2002	Cautreels <i>et al.</i>
	AB4	2002/0086880 A1	07-04-2002	Rubin <i>et al.</i>
	AG4	2002/0086881 A1	07-04-2002	Rubin <i>et al.</i>
	AD4	2002/0107244 A1	08-08-2002	Howard, Jr.
	AF4	2003/0125349 A1	07-03-2003	Cautreels <i>et al.</i>
	AF4	2003/0203055 A1	10-30-2003	Rao <i>et al.</i>
	AG4	6,593,336 B2	07-15-2003	Mangel <i>et al.</i>
	AH4	2003/0036549 A1	02-20-2003	Mangel <i>et al.</i>
	AI4	6,211,171 B1	04-03-2001	Sawynok <i>et al.</i>
	AJ4	5,530,008	06-25-1996	Azcona <i>et al.</i>
	AK4	5,977,127	11-02-1999	Bonnacker <i>et al.</i>
	AA5	4,845,092	07-04-1989	Sanger <i>et al.</i>

EXAMINER

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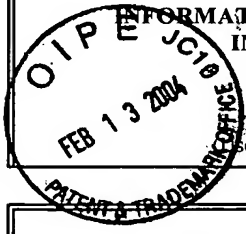
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FOREIGN PATENT DOCUMENTS

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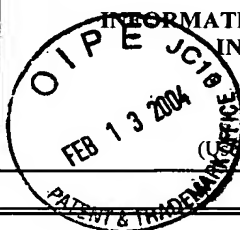
PTO-1449 REPRODUCED  INFORMATION DISCLOSURE CITATION IN AN APPLICATION February 11, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3506.1000-002	APPLICATION NO. 10/757,364	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Depoortere, I., <i>et al.</i> , "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis ¹ ," <i>J. Pharmacol. Exp. Ther.</i> , 294(3): 983-990 (2000).
AS	Million, M., <i>et al.</i> , "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," <i>Amer. Phys. Soc.</i> , 276 (4 Pt 1): G1027-G1036 (1999).
AT	Owens, M. J., <i>et al.</i> , "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites ¹ ," <i>J. Pharmacol. Exp. Ther.</i> , 283(3): 1305-1322 (1997).
AU	Kozlowski, C.M., <i>et al.</i> , "The 5-HT ₃ Receptor Antagonist Alosetron Inhibits the Colorectal Distention Induced Depressor Response and Spinal <i>c-fos</i> Expression in the Anaesthetised Rat," <i>Gut</i> , 46: 474-480 (2000).
AV	Ito, C., <i>et al.</i> , "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]-benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine ₃ Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).
AW	Eguchi, J., <i>et al.</i> , "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hydrochloride," <i>Arzneimittelforschung</i> , 47(12): 1337-1347 (1997).
AX	Venkova, K., <i>et al.</i> , "Peripheral Activity of a New NK ₁ Receptor Antagonist TAK-637 in the Gastrointestinal Tract," <i>J. Pharmacol. Exp. Ther.</i> , 300(3): 1046-1052 (2002).
AY	Yuan, S.Y., <i>et al.</i> , "Investigation of the Role of 5-HT ₃ and 5-HT ₄ Receptors in Ascending and Descending Reflexes to the Circular Muscle of Guinea-pig Small Intestine," <i>Br. J. Pharmacol.</i> , 112(4): 1095-1100 (1994).
AZ	Jin, J.G., <i>et al.</i> , "Propulsion in Guinea Pig Colon Induced by 5-Hydroxytryptamine (HT) Via 5-HT ₄ and 5-HT ₃ Receptors ¹ ," <i>J. Pharmacol. Exp. Ther.</i> , 288(1): 93-97 (1999).
AR2	Greenbaum, D.S., <i>et al.</i> , "Effects of Desipramine on Irritable Bowel Syndrome Compared with Atropine and Placebo," <i>Digestive Diseases and Sciences</i> , 32(3): 257-266 (1987).
AS2	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996.

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION February 11, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3506.1000-002		APPLICATION NO. 10/757,364	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AT2	Eguchi, J., <i>et al.</i> , "The Anxiolytic-Like Effect of MCI-225, A Selective NA Reuptake Inhibitor with 5-HT ₃ Receptor Antagonism," <i>Pharm. Biochem. and Behavior</i> , 68:677-683 (2001).
AU2	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> , 3:104-110 (2001).
AV2	Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," <i>Gut</i> 51(1):81-86 (2002).
AW2	Camilleri, M., "Serotonergic Drugs: Emerging Therapies for Irritable Bowel Syndrome," In <i>Irritable Bowel Syndrome a Clinician's Guide</i> , M. Camilleri and R. C. Spiller, eds., Chapt. 19; pp 1-10 (2002).
AX2	Wood, J.D., <i>et al.</i> "Fundamentals of Neurogastroenterology," <i>Gut</i> 45(2):II6-II16 (1999).
AY2	Burns, M.J., "The Pharmacology and Toxicology of Reboxetine," <i>Int. J. Med. Toxicol.</i> 3(4):26 1-8 (2000).
AZ2	Thompson, W.G., <i>et al.</i> , "Functional Bowel Disorders and Functional Abdominal Pain," <i>Gut</i> 45:II43-II47 (1999).
AR3	Sheikh, M. Y. and Wright, R.A., "Irritable Bowel Syndrome: Current Concepts and Future Prospects," <i>Hospital Physician</i> , pp. 31-38 (March 1999).
AS3	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> 3:104-110 (2001).
AT3	Gebhart, G.F., "Pathobiology of Visceral Pain: Molecular Mechanisms and Therapeutic Implications IV. Visceral Afferent Contributions to the Pathobiology of Visceral Pain," <i>Am. J. Physiol. Gastrointest. Liver Physiol.</i> 278:G834-G838 (2000).
AU3	Mertz, H.R., "Irritable Bowel Syndrome," <i>N. Engl. J. Med.</i> 349:2136-2146 (2003).
AV3	Bymaster, F.P., <i>et al.</i> "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters <i>In Vitro</i> and <i>In Vivo</i> , Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," <i>Neuropsychopharmacology</i> , 25(6):871-880 (2001).
AW3	Béïque, J.C., <i>et al.</i> , Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349(1):129-132 (1998).

EXAMINER	DATE CONSIDERED
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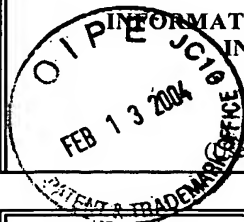
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AX3	Wong, E.H.F., <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psychiatry</i> , 47(9): 818-829 (2000).
AY3	Sach, J.A., <i>et al.</i> , "Irritable Bowel Syndrome," <i>Curr. Treat. Options. Gastroenterol.</i> , 5(4): 267-278 (2002).
AZ3	Angel, I., <i>et al.</i> "Litoxetine: A Selective 5-HT Uptake Inhibitor with Concomitant 5-HT ₃ Receptor Antagonist and Antiemetic Properties," <i>Eur. J. Pharmacol.</i> , 232(2-3):139-145 (1993).
AR4	Fairweather, D.B., <i>et al.</i> , "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," <i>Br. J. Clin. Pharmacol.</i> , 40(2):119-125 (1995).
AS4	Morteau, O., <i>et al.</i> , "Influence of 5-HT ₃ Receptor Antagonists in Visceromotor and Nociceptive Responses to Rectal Distension Before and During Experimental Colitis In Rats," <i>Fundam. Clin. Pharmacol.</i> , 8(6):553-562 (1994).
AT4	Goldberg, P.A., <i>et al.</i> , "Modification of Visceral Sensitivity and Pain in Irritable Bowel Syndrome by 5-HT ₃ Antagonism (Ondansetron)," <i>Digestion</i> , 57(6):478-483 (1996).
AU4	LOTRONEX - Tablets, <i>Product Information</i> , GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).
AV4	"Irritable Bowel Syndrome at a Glance - Nosology, Epidemiology, and Pathophysiology (Monograph I), December 2002 [Retrieved on 2002-12-12]. Retrieved from the Internet <URL:http://fdhn.org/html/education/gi/ibs_nosology.htm>
AW4	U.S. Provisional Application No. 60/364,531, filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 (Reference AQ2) and U.S. 2003/0203055 A1 (Reference AF4).
AX4	GB 0304648.9, filed 02-28-2003, entitled "New Therapeutic Use of 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperziny) Thieno[2,3-D] Pyrimidine," priority document for WO 2004/004734 A1 (Reference AL2).
AY4	GB 0216027.3, filed July 10, 2002, entitled "New Therapeutic Use," priority document for WO 2004/004734 A1 (Reference AL2).
AZ4	Drossman, D.A., <i>et al.</i> , "Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development," <i>Gastroenterology</i> , 112: 2120-2137 (1997).

EXAMINER

DATE CONSIDERED